REMARKS

I. Amendment to the Claims

Upon entry of the foregoing amendment, claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80, and 82-90 will remain pending. All of these claims stand rejected. Applicant still reserves all rights to pursue protection for the subject matter of all previously cancelled claims in future patent applications. Claim 9 is amended to clarify that the meaning of increased resistance to add the words of urine. This change should obviate the 112 second paragraph rejection. Claim 85 is amended herein without prejudice, in order to expedite allowance, to delete the word "adequate".

Applicant respectfully requests entry of the above Amendments and submits that the Amendments do not introduce new matter.

Based on the above amendment, and the remarks below, Applicant respectfully submits that the claims are in condition for allowance. Applicant respectfully requests reconsideration of the rejections and that all of the pending claims be passed to issue.

II. Rejection Under 35 U.S.C. § 112

Second Paragraph (Definiteness)

Claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 82-84, 80 and 86-90 stand newly rejected for allegedly failing to comply with the definiteness requirement of 35 USC 112 second paragraph.. *See* Office Action, p. 9. The Office Action alleges that Claim 9 is unclear in the recitation "increasing resistance of passage through a urethra". While it is submitted that the meaning thereof would have been clear to one skilled in the art, in order to expedite prosecution claim 9 has been amended to add the words "of urine" to make explicit that the increased resistance refers to the reduced passage of urine through the urethra as a result of the recited administered prosthetic device comprising a hydrogel. As this amendment was suggested by the Examiner, it is believed that this change should overcome the 112 second paragraph rejection. Withdrawal of the 112 second paragraph rejection of claims 9-17, 29-32, 34-38, 52-53, 62, 67-69, 82-84 and 86-90 is therefore respectfully requested.

III. Rejection Under 35 U.S.C. § 103

The examiner bears the initial burden of establishing a *prima facie* case of obviousness. If the examiner does not satisfy his/her burden, then the applicant is not obligated to submit evidence of nonobviousness. *See* M.P.E.P. § 2142.

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

See id.

A. Pavlyk in View of Sknar and Further in View of Applicant's Admission and Annis

Claims 9-17, 29-32, 34-38, 52-53, 62, 67-69 and 78-80 and 82-90 were rejected for allegedly being unpatentable over U.S. Patent No. 5,798,096, in issued to Pavlyk ("Pavlyk"), in view of Russian Application No. 2148957, in the name of Sknar, *et al.* ("Sknar"), and further in view of Applicant's admission in an Examiner interview held on February 23, 2006 and in a Response filed February 27, 2006 ("Applicant's Admission" and further in view of Annis et al (US Patent No. 4,857,041).). *See* Office Action, pp. 3-5. Applicant respectfully traverses the rejection.

Pavlyk describes a polyacrylamide hydrogel comprising 3.5% to 9.0% cross-linked polyacrylamide for cosmetic procedures, such as for bulking of the penis, rectomammarily for bulking of breasts, and for filling in wrinkles. In addition, Pavlyk clearly teaches that "[c]oncentrations below 3.5% make the hydrogel unstable . . . while concentrations above 6.0% decrease fluidity of the hydrogel practically to zero and is practicable in manufacturing firm, form-retaining, precast endoprosthesis." Col. 3, ll. 46-52. Moreover, in the procedures described in Pavlyk, the prosthetic device performs no physiological/biological function. Even more specifically, there is no teaching to use a polyacrylamide hydrogel for treating urinary incontinence by urethral bulking.

Sknar discloses the administration of "Interfall" polyacrylamide gel, which is a gel within the scope disclosed by Pavlyk, into the ostium of the ureter for the treatment of vesicouretal reflux ("VUR"). Sknar, however, is not directed to the treatment of urinary incontinence. VUR and urinary incontinence are unrelated, both clinically and anatomically. VUR is a reflux from the "top" of the bladder back up through the ureter(s) to one or both of the kidneys, which may cause severe kidney infections. A normal, healthy flow of urine begins at the metabolic processes of the kidneys, and then passively flows or drips down from each of the kidneys through each of the ureters into the bladder. Sknar describes a relatively passive role of the gel, whereby the gel "plugs" the ureter to non-therapeutically, but non-intrusively, partially impede the normal passive flow of urine from the kidney down through the ureter and then to the bladder. Due to its positioning at the mouth between the ureter and the bladder, the gel plays its passive therapeutic role to prevent the reflux of urine from the top of the bladder and up the ureter.

Annis et al discloses a prosthetic material and use thereof for elevating the urethra which as discussed below, and contrary to the Office Action, does not teach or suggest the claimed invention as the Annis prosthetic is rigid and does not comprise a viscous, injectable polyacrylamide hydrogel as in the invention. Rather, as noted below, the Annis reference makes abundantly clear based on numerous statements that the product described by Annis is non-fluid (solid) and does not possess the complex viscosity properties of the subject polyacrylamide hydrogel which are recited in the claims under rejection. Also, the Annis reference does not teach or suggest the administration of their solid prosthetic material into the urethra as in the present claims. .Further the Annis et al reference does not teach or suggest the use of their solid prosthetic device for urethral bulking as recited in the present claims.

As reflected by the claims under examination , the present invention is directed to the treatment of urinary incontinence by bulking the urethra, (which is found at the lower end of the bladder). Therefore, the urethra is at the opposite end of the bladder from the ureter, the later being the focus of the treatment for VUR, whereas the former being the focus of the present invention. Specifically, the ureters lead from the kidneys to the bladder whereas the urethra leads out from the bladder to empty the bladder in the active process of urination. In urinary incontinence, the voluntary muscles (sphincters) of the urethra have weakened to the point of being ineffective and/or the urethra has lost its internal shape, folds, and ridging, often due to age. The active processes of urination and urine retention are no longer under the voluntary

control of the sufferer. This is accomplished by bulking the urethra with a prosthetic device comprising a viscous injectable polyacrylamide hydrogel possessing the recited complex viscosity properties. This treatment is not taught or suggested by the prior art references taken singularly in combination. In fact for the reasons set forth herein and previously the references are remote from the claimed invention, are not properly combined and provide no incentive to modify the contrary teachings contained therein to arrive at the invention. actually would teach away from the present claimed invention Applicants turn now to the specific reference teachings, and how they do not suggest the claimed invention.

Sknar describes the treatment of VUR in Example 1; however in the Example, a child diagnosed with VUR and pyelonephritis (inflammation of the kidneys, pelvis, and calices) also complained of urinary incontinence. The child was treated for VUR by injecting the gel into the ureter. Months later, the child had "no complaints." Although VUR is unrelated clinically and anatomically to urinary incontinence, the treatment of VUR by injecting the gel into the ureter seemed to alleviate urinary incontinence in the child. The most plausible explanation for this observation is that the bed-wetting was due to the infected and irritated bladder caused by the VUR. The irritated bladder must have then lead to incontinence. One or ordinary skill in the art would recognize that injections into the ureter are not a means for treating urinary incontinence. Moreover, a skilled artisan would well know that the ureter and urethra are anatomically distinct organs that are situated at different sites and that the effect of injection of a prosthetic device or material into the urethra and the ureter can not be equated. Nor can the effects thereof be equated.

Moreover, even assuming (erroneously) that they were equivalent, there is no teaching in Sknar to treat urinary incontinence by bulking the urethra with their polyacrylamide hydrogel.

Although Sknar teaches the use of a gel within the disclosure of Pavlyk for the treatment of VUR, the combined teachings of Pavlyk and Sknar still do not provide any motivation or suggestion to carry out urethral bulking by using their polyacrylamide hydrogel. First, aside from the fact that these are distinct organs of the body with different functions (although both are part of the urinary system), from a practical and medical point of view, given the "passive" versus "active" functions of the ureter compared to the urethra, the treatment of urinary incontinence is of a far higher degree of complexity than the treatment of VUR. Contrary to the ureter, the urethra is involved in both the voluntary retention of urination and in the voluntary

urination whereas the ureter is involved in only the involuntary, passive flow of urine into the bladder. The musculature in the urethra involved in voluntarily retaining urine and voluntarily urinating is subtle, yet significant. The complexity of the control of this musculature under stress and urge is likened to keeping one's balance on a bicycle: it is difficult to learn for children and often lost in the elderly. This complexity is not found in the passive function of the ureter. A material used for urethral bulking must be able to 1) functionally adapt as the muscles of the urethra contract and relax, 2) fill the lost or deformed folds within the urethra, and 3) provide resistance by bulking. Of equal importance to retaining urine in the treatment of urinary incontinence is the need to allow for voluntary urination. Therefore, the material used for the treatment of urinary incontinence must provide a sufficient balance of elasticity and viscosity. Because these requirements are not found in the material used for the treatment of VUR, one of ordinary skill in the art would not reasonably expect to successfully use a material for the treatment of VUR as the material for the treatment of urinary incontinence.

Also, the deficiencies of Pavlyk and Sknar are not cured by Annis. To the contrary, as discussed above, and in further detail below, it is absolutely clear from Annis that their invention instead relates to a rigid (solid) prosthetic material which unlike the present invention is not viscous, is not injectable, and is placed outside of the urethra in order to elevate same (rather than placed within by injection as in the present invention.

Also, the reference contains no statements which would motivate a skilled artisan to modify their prosthetic material (to make it viscous) or to instead place their material within the urethra in order to achieve urethral bulking. Indeed this reference is believed to be totally distinct from the claimed invention.

For similar reasons, the combined teachings of Pavlyk and Sknar and Annis do not teach or suggest each of the claimed limitations. The present invention requires either bulking of the urethra, injecting the hydrogel in the urethra, or increasing resistance of passage through the urethra, none of which are disclosed in Pavlyk or Sknar or Annis.

For at least the aforementioned reasons, the *prima facie* case of obviousness has not been established. Therefore, the combination of Pavlyk and Sknar and Annis do not render the present invention obvious under 35 U.S.C. § 103. Also, contrary to the Office Action, at no time did Applicants admit that any piece of prior art suggested use of a hydrogel as used in the present invention for effecting urethral bulking. (In fact given the distinct properties of the

subject hydrogel versus previously used materials and devices a prosthetic device comprising such material will require regulatory review by the Food and Drug Administration to confirm its in vivo suitability and efficacy prior to its usage in the United States.)

The Examiner considered arguments similar to the foregoing arguments and nevertheless has maintained the obviousness rejection (now combined with Annis). Applicants respectfully but vehemently traverse.. The asserted rationale concerning Pavlyk is that while the Examiner concedes that the Pavlyk reference does not teach or suggest that their acrylamide is to be used for treating urinary incontinence, "that is why the rejection is made in combination with other references, such as applicants admitted prior art and Annis". She asserts in her rejection that "one having ordinary skill in the art would have been motivated to inject the acrylamide hydrogel [of Pavlyk] into the ostium of the ureter or the urethra with the expectation that the hydrogel would act as a bulking material that would create increased resistance to the flow [of] urine in the urethra or the ureter that would lead to the treatment of urinary incontinence" (see page 5, lines 6-10 of Final Rejection).

Applicants respectfully submit that the Examiner's asserted rationale for the obviousness rejection is improper. As previously explained the device of Pavlyk is a cosmetic device for enlarging or bulking of the penis and similar cosmetic bulking applications. Particularly, it provides a cosmetic effect in that it provides for penile or other cosmetic (not therapeutic) enlargement but does not elicit any biological effect thereon. Contrary to the rejection one skilled in the art would not be motivated to look to the cosmetic art, or more particularly penile enlarging devices and materials and reasonably conclude that such devices or materials could or should alternatively be used as urethral bulking agents. Also, whether the hydrogel of Pavlyk would "inherently" possess such capability is irrelevant to the obviousness rejection because the reference alone or in combination with Sknar, Annis or Applicant's alleged admission as none of the foregoing would motivate the skilled artisan to use such hydrogel as claimed herein. The Examiner has pointed to no piece of prior art which would reasonably suggest that materials used for penile enlargement (or the other cosmetic bulking usages) and urethral bulking are "interchangeable" as seemingly suggested by the Examiner and that a material that provides for penile (or breast) bulking would predictably be useful in effecting urethral bulking and yield the desired functional effect (treat urinary incontinence).

Also, contrary to the rejection, this usage would not have been obvious based on prior usage of other polyacrylamides as disclosed in the prior art. With respect thereto, it was generally known in the art at the time of filing of the application that a significant problem associated with the use of polyacrylamides for in vivo clinical usage, i.e., in contexts such as herein wherein they are inserted or injected into the body (urethra), is the fact these materials can give rise to toxicity (because of the potential presence of an excessive amount of residual monomers remaining after the polymerization process has been completed). Moreover, these toxic effects (attributable to monomers) especially could cause dire effects on functional organs such as the urethra and neighboring organs.

With respect thereto, it would appear from the rejection that the Examiner in considering the teachings of the Pavlyk reference has concluded that the disclosed reaction of the acrylamide monomer and the methylene bis-acrylamide monomers has necessarily gone to completion. However, Applicants have carefully reviewed this reference and can find no basis for this conclusion. Certainly there is no express statement to that effect in the reference. Indeed, these reactions do not go to 100% completion. Hence the reason for the vigorous washing step which is required, as described in this application.

In addition, the Examiner has not provided any technical basis for coming to this conclusion which for the reasons discussed is not technically sound. Without any evidence or scientific basis to infer that this is the case it is completely unreasonable for the Examiner to conclude that the Pavlyk hydrogel would be suitable for use as a urethral bulking device or possess the properties of the inventive hydrogel.

In addition, the rejection is respectfully submitted to be improper since the rejection seems to mischaracterize the teachings of RU 2,148,957 reference (Sknar). Particularly, the Examiner suggests that the Pavlyk gel was known for injecting into the ostium of the ureter for the treatment of urinary incontinence as substantiated by Sknar. However, Applicants respectfully submit that this conclusion is erroneous. It would seem that the Examiner has again equated treatments which involve devices for insertion in the ureter and the urethra. However, this is scientifically invalid. Those skilled in the pertinent art are well aware that injection of a device or material into the ureter is not equivalent to injection of such device or material into the urethra and moreover that injection into the ureter does not provide an effective treatment of

urinary incontinence as it is a passive organ and consequently does and can not provide for the active regulation of urine flow .

Rather, the ureter merely provides the physical connection between the kidneys and the bladder, whereas urinary incontinence involves problems beneath the bladder. (It can be equated to a pipe). With respect thereto it should be noted that the instant claims provide for implanting the hydrogel containing prosthetic device in the urethra so that it creates resistance which impedes the passage of urine through the urethra. By contrast, the indication treated by Sknar involves implantation of their prosthetic device at an anatomically distinct site of the body which moreover provides for the treatment of a different condition. i.e. vesico-uretal reflux. Therefore, in contradistinction to the rejection, Applicant's "admission" with respect to the prior art (Sknar reference) does not teach or suggest the treatment of urinary incontinence by creating resistance in the urethra and thereby impeding the passage of urine as claimed.

Therefore, while Applicants concede that urinary incontinence is mentioned in Example 1 of Sknar, the effected treatment was for another clinically distinct and actually diagnosed condition, i.e., vesico-uretal reflux and is not suggestive of the inventive methods. Also, since the Sknar method did not involve creating resistance in the urethra there is further no basis for concluding that the presently claimed methods of treating urinary incontinence are inherent to Sknar's disclosed treatment. (Certainly the inventors do not state as such and the fact that the one patient (child) in example 1 indicated no complaints after treatment is further not suggestive since the treatment did not placement of their device such that it would result in creating resistance in the urethra. Such an inference of inherency is misplaced as administration of these devices occurs at different sites of administration as explained above (and as reflected by the subject claims) .

Applicants respectfully submit that the rejection is unsustainable as it ignores or at least does not take into account the express limitations of the claims which require that the administered prosthetic device create resistance in the urethra which inhibits the passage of urine. Simply put injection or insertion of a device into the ureter versus the urethra and the effects thereof are not equivalent.

As noted above, the Examiner has further cited Annis and suggests that this reference compensates for the deficiencies of Pavlyk and Sknar. Particularly, the Examiner has relied on Annis to support her conclusion of "inherency" However, Applicants respectfully submit that

there is no basis for "inherency". In fact, careful review of the teachings of this reference leads to the inevitable conclusion that Annis teaches a prosthetic material very different from the viscous hydrogel used in the claimed methods and further that the use of Annis' device is not inherently the same as the inventive treatment methods (urethral bulking which effectively treats urinary incontinence.). With respect thereto the Examiner states in the final rejection that "it is known in the art that urinary incontinence is treated by administering prosthetic device comprising polyacrylamide hydrogel into the urethra" However, this is not true (nor was it admitted by Applicant). For one thing, as noted above, the product disclosed by Annis is not an injectable polyacrylamide and it does not possess the complex viscosity recited in the present claims. Secondly, the material used by Annis is not administered into the urethra. Thirdly, the technology of Annis is not even intended for urethral bulking (which is perhaps not surprising since the disclosed polyacrylamide would not be anticipated to be suitable for such use given its physical properties (rigid solid material)).

Again Applicants respectfully submit that the Examiner is ignoring or has not given the appropriate consideration of explicit limitations recited in the claims under rejection. Particularly, the nature of the prosthetic material used in the invention is a viscous, injectable material (see viscosity parameter limitations recited in claim 9) which based thereon can be loaded into a syringe and extruded out of a needle. This desired property (injectability) is inherent to the hydrogel of the claimed invention because of the defined, complex viscosity (see claim 9) which is clearly provided for in each of the independent claims herein. (See e.g., claims 78 ad 79 which include the term "injecting" which is feasible based on these complex viscosity properties) By contrast, the product of Annis is not suitable for injection as it is a rigid non-fluid material. This is quite clear based on numerous statements in the reference. For example, Annis note that their material has physical properties which provide for "tear resistance for the purposes of its securement by suture during surgery" and for the "provision of localized reinforcement at appropriate edge portions of the body, typically by embedding plastic material mesh in the hydrogel during its preparation".

In addition, it is clear that the Annis material is solid as it possesses a "body" with a defined shape and size (not a fluid which has an undefined structure) , and is clear from column 2, lines 57-61 wherein they refer to its preferable "kidney shape typically 5x3x1 cms, although it may be appropriate to provide other sizes". Clearly, based at least on these recitations the Annis

material is a solid and does not possess the fluid viscosity properties of the injectable hydrogel used in the present invention.

Again, it would appear from the stated rationale for the rejection that the Examiner has failed to take into account claim limitations involving the specific nature of the polyacrylamide hydrogel used in the claimed invention but rather has equated the properties of the polyacrylamide of Annis and that used in the invention. However, tit is well known to those skilled in polymers that the viscosity properties of polyacrylamide polymers may vary substantially depending on parameters such as the molecular weight content, crosslinking density, processing conditions, and other numerous polymerization effecting parameters. Based thereon, it can not be inferred that the recited complex viscosity of the inventive polymeric polyacrylamide hydrogel is inherent to Annis especially as the reference contains explicit statements attesting to its solid nature which indicate that the Annis acrylamide material is very different than the hydrogel used in the invention. As explained previously, it is this complex viscosity which provides for the correct combination of elasticity within the urethra and conveys the desired bulking properties , i.e., resistance to pressure.

Yet another distinction in Annis vis-à-vis the invention is the fact that the subject prosthetic device is injected into the urethra so as to achieve the desired bulking, whereas in Annis the disclosed solid polyacrylamide body is placed proximal to the urethra by "opening the interior vaginal wall longitudinally and separating the vaginal tissue from the bladder and urethra to all access the desired site". (see column 3, lines 17-21 of the reference). Therefore, it is clear at least based thereon that the Annis device is not located within the urethral channel or passage but rather is outside the channel so that it functions as a cuff or pedestal which acts to elevate the urethra. This is also clear by virtue of the fact that Annis disclose that their device may be tethered to pelvic ligaments or the rectal sheath, again making clear that it is a solid material which is not injectable into the urethra as with the inventive hydrogel, possessing the afore-discussed complex viscosity properties, as recited in the rejected claims.

There is no teaching in Anis which would suggest modification of their disclosed methods of administration or their polymeric materials in order to achieve urethral bulking and increased resistance of passage [of urine] through the urethra as effected in the present invention. Rather, Annis relates to a very different surgical procedure militated by the very distinct (solid) properties of their polyacrylamide body versus the subject polyacrylamide hydrogel with

complex viscosity properties. As explained, in the Annis methods the urethra is elevated (by the cuff or tethered body) resulting in the control or passage of urine by a very different mechanism than in the invention. Their prosthetic device transmits abdominal pressure to the proximal part of the outlet of the bladder, the urethra, enabling the pressure acting on the urethra from without the same to rise corresponding with that acting on the urethra from within This mechanism requires that the urethra be positioned within the abdominal pressure zone by elevating the urethra. Moreover, this mechanism requires that their device be located external to the urethra as shown in Figure 4 of the reference.

Therefore, Annis actually teaches away the claimed invention because changing the orientation of their device such that it is oriented internal to the urethra (as in the present invention) rather than on the outside would not achieve their expressly desired result, i.e., elevation of the urethra, which is required for the operability of their distinct surgical methods.. Therefore, Annis contains no teaching which would suggest an injectable hydrogel or its use injected into the urethra to achieve urethral bulking as in the present invention. Likewise, for the reasons afore-discussed Pavlyk and RU 2,148,757 (Sknar) also do not teach or suggest the invention as these references separately or in combination fail to each or suggest a polyacrylamide hydrogel having the recited complex viscosity properties of the invention or its use to effect urethral bulking as claimed.

As a final note with respect to this rejection it is again respectfully noted that the Examiner concludes that Applicants have admitted that the prior art, e.g., the Pavlyk reference, teaches a product that would impede the flow of urine in the urethra. This is not correct. As explained supra, Applicants have instead argued that Pavlyk relates to the passage of urine through the ureter which occurs via a passive process between the kidney and the bladder. There are no voluntary muscles that are involved, and there is no pressure buildup. This is very different from the invention which instead involves urethral bulking capacity that creates resistance to the flow of urine and which can not be equated to the passive passage of urine in the ureter.

B. Vogel in View of Sknar and Further in View of Applicant's Admission

Claims 9-17, 29-32, 34-38, 52-53, 62, 67-69, 78-80 and 82-90 also stand rejected for allegedly being unpatentable over U.S. Patent No. 6,335,028, in issued to Vogel ("Vogel"), in view Sknar and further in view of Applicant's Admission. *See* Office Action, pp. 6-7. Applicant respectfully traverses the rejection.

As previously explained, Vogel discloses solid microparticles that maintain their shape when implanted and a liquid suspension of the microparticles. *See* Vogel, col. 6, ll. 20-23 and 52-55. The present invention, on the other hand, is directed to a pliable hydrogel that takes the shape of the cavity in which it is administered. This property of the hydrogel is recited in the claim as a complex viscosity of about 2 to 50 Pas, which provides for a colloidal solution. While Vogel does not disclose the complex viscosity of the solid microparticles described therein, the complex viscosity of the microparticles would likely be significantly greater than 50 Pas due to their solid state. Moreover the liquid suspension for injection, which comprises the microparticles, would not have a *complex* viscosity. Instead, it would only have a viscosity due to its fluid nature. Although the prosthetic device of the present invention does not exclude a hydrogel suspended in a liquid, the claim recites that the hydrogel, not the prosthetic device, has a complex viscosity of 2 to 50 Pas. Based on at least the foregoing Vogel does not teach or suggest each of the claim limitations.

The suspension disclosed by Vogel can be analogized to marbles in water whereas the material used in the present invention can be compared to molten glass. Molten glass would be described as possessing "complex viscosity" whereas marbles in water (marbles still being made of glass) would be described simply based on its viscosity. The terms "complex viscosity" and "viscosity" are not interchangeable and a person skilled in the art, when reading the term "complex viscosity" in the context of the present invention would readily comprehend that this pertains to a fluid solid rather than a suspension of particles or a liquid.. Therefore, the physical properties and material nature of the Vogel product is different than the inventive viscous hydrogel and instead refers to a heterogeneous prosthetic whereas the invention instead relates to a homogeneous polymeric material (based on the recited means for preparation).This significant distinction is clearly conveyed by the recitation "complex viscosity" which is not applicable to the Vogel product.

Rather, in Vogel the microparticles are in suspension and the polyacrylamide hydrogel of Vogel is solid in nature. This is clearly conveyed by the fact that their product may comprise up to 50% of the crosslinking agent methylene bis-acrylamide. This will result in a high crosslinking density which in turn will yield particles solid in nature, which do not possess the complex viscosity required by the hydrogel recited in claimed invention (and which property renders it injectable as reflected by the subject claims).

It is quite clear that these are solid particles since Vogel defines these particles as having a finite size and shape as disclosed at page 6, lines 24-31 of the reference. Similarly, at column 6, lines 43 they refer to "microparticles, or other solid substrates". Their use of the term "solid" makes it abundantly clear that the Vogel microparticles are solid and that this suspension cannot be defined by the rheological descriptor "complex viscosity".

Also, while Vogel has not limited the chemical nature of their disclosed beads to methaacrylamide polymers, in contradistinction to the statement in the Office Action the disclosed formation of a polymer will not lead to a polyacrylamide possessing the properties of that recited in the present claims. Methacrylamide is a separate chemical entity versus acrylamide with distinct polymerization properties and physical characteristics. Again, the Examiner has seemingly erroneously suggested that the reference inherently teaches a polymeric hydrogel as used in the present invention without any rationale scientific basis and explicit statements to the contrary in the reference. Not only does the reference not teach a polymeric hydrogel possessing the rheological properties as in the present invention; it instead even relates to a hydrogel comprised of a different polymer. Moreover, one skilled in the art would not have been motivated to administer the hydrogel of Vogel, as in the claimed urethral bulking methods, since it is a suspension of microbeads.

The Examiner at page 8 further states with respect to Vogel that the reference would inherently teach a polymer as claimed in the present invention that possesses complex viscosity . However, this is incorrect because as explained, it is clear from explicit statements in the reference that it instead relates to solid particles (not an injectable hydrogel having the properties of the present invention that allow for its use to achieve urethral bulking).

Vogel is again combined with the RU'357 reference (Sknar). For the same reasons as set forth in the traversal of the first obviousness rejection, this reference is not suggestive of the invention Also, the Examiner again relies on Annis to allegedly cure the deficiencies of Vogel

and Sknar references. Annis is discussed above in detail in the traversal of the previous obviousness rejection. As discussed at length this reference relates to a very different material produced by an entirely different method which is in turn used for an entirely different biological purpose.

The combination of Vogel and Sknar and Sknar also does not teach or suggest each of the claim limitations. The hydrogel disclosed in Sknar, as discussed above, or the polymeric prosthetic device of Annis does not provide for the missing claim limitation in Vogel, namely a polyacrylamide hydrogel complex viscosity or its use injected in the urethra to effect urethral bulking.

Furthermore, one of ordinary skill in the art would not be motivated to use the hydrogel disclosed in Sknar or Annis for the urinary incontinence treatment of Vogel because of the difference in the passive function of the ureter and the active function of the urethra, as discussed above. Finally, even if one of ordinary skill in the art were to combine Sknar and Vogel and Annis , he/she would not have a reasonable expectation of success due to the vast difference in using the solid microparticles of Vogel for the treatment of urinary incontinence, which is an "active" function, and using the gel of Sknar for the treatment of VUR, which is a "passive" function. or the solid material of Annis which is used outside the urethra to elevate same.

Particularly, for the same reasons articulated above in the traversal of the first obviousness rejection, the addition of Annis to the afore-discussed references also does not teach or suggest the invention. Moreover, the rejection is incorrect at page 8 in asserting that Annis teaches administering their device into the urethra. Rather as explained above, and supported by the explicit teachings of Annis, their prosthetic device is not placed into the urethra but rather is placed outside of the urethra such that it raises the urethra and thereby provides for the treatment of a distinct condition from urinary incontinence, i.e., vesico-uretal reflux. As explained above these are distinct medical conditions which may be treated using distinct materials and methods.

For at least the aforementioned reasons, the *prima facie* case of obviousness has not been established. Essentially, contrary to the position taken by the Examiner, one skilled in the art would not have had incentive to administer the hydrogel of Vogel since it is suspension of microbeads, based on the teachings of Annis would not be so motivated since their material is a solid and is placed at a site outside the urethra to achieve the disclosed surgical objective; and

based on RU'357 would not be so motivated since it does not suggest a polyacrylamide hydrogel having complex viscosity as in the present invention. Also, the rejection deficiencies are not cured by any statements made by Applicant in the specification or prosecution of this application.

Therefore, the combination of Vogel and Sknar and Annis do not render the present invention obvious under 35 U.S.C. § 103. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

As a final note, Applicants acknowledge the Examiner's suggested amendment to "place the case in condition for allowance". This amendment would require recitation of a geometrical limitation into the claims with respect to the insertion of the viscous hydrogel While Applicants appreciate the Office's suggestion, this limitation is not required to distinguish over the prior art, nor is it a limitation required for practice of the claimed invention. Indeed it is well known that functional language is permissible as long as the metes and bounds of the claims would be readily understood and could be practiced based on the teachings of the application absent undue experimentation. This is more than adequately satisfied herein.

IV. Request for Examiner Interview

For at least the reasons stated above, the rejections have been properly traversed, accommodated or rendered moot. Thus, Applicant respectfully submits that claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80, and 82-90 are in condition for allowance. Accordingly, Applicant respectfully requests that the Application be allowed and passed to issue.

In the event any outstanding issues remain and the Examiner determines the claim are not in condition for allowance, Applicant hereby requests a personal Examiner Interview. Applicant would appreciate the courtesy of a telephone call to Applicant's representative to schedule the interview. Because of the new continuation rules (which significantly limit the number of continuations which may be filed) and further in view of the prolonged prosecution of this application, Applicants would like to schedule this interview prior to October 28, 2007 to give Applicant sufficient time to formulate their further continuation strategy, if required.

V. CONCLUSION

The Commissioner is hereby authorized to charge Deposit Account No. 50-0206 in the amount of $810.00 to cover the fees for this RCE. However, in the event it is determined by the USPTO that a variance exists between the amount due and the amount authorized above, the Commissioner is hereby authorized to debit or credit any such variance to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,
HUNTON & WILLIAMS LLP

Date: 10/8/07

By: 
Robin L. Teskin
Registration No. 35,030

Hunton & Williams LLP
Intellectual Property Department
1900 K Street, N.W.
Suite 1200
Washington, D.C. 20006-1109
Ph. (202) 955-1500
Fax (202) 778-2201